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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,486	11/20/2000	Chet M. Crump	BAL-66-CON	8937

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EXAMINER	
WEISS JR, JOSEPH FRANCIS	
ART UNIT	PAPER NUMBER
3761	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/716,486	Applicant(s) Crump et al.
	Examiner Joseph Weiss	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 25, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-12* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☑ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-7, 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann et al (US 5354267) in view of Russo (US 5775325).

In regards to claim 1, Niermann discloses a respiratory suction apparatus (10) comprising a suction catheter (18) for removing fluids from a respiratory tract of a patient by insertion of the distal end (see fig 1, portion of 18 within elements 35 & 75) of the catheter into a patient's respiratory tract and withdrawal of the distal end of the catheter through a portion of the tract while applying negative pressure to the lumen of the catheter (see the background & summary of the invention); a protective sleeve (20) surrounding a proximal longitudinal portion of the catheter; a distal adapter (16) configured for fluid communication with a manifold (14) of a patient's artificial airway; a collar (32) disposed within the adapter and partially surrounding the distal end of the catheter when the catheter is withdrawn from the manifold, the catheter and the collar defining a substantially uniform cylindrical space around the distal portion of the catheter, the cylindrical space capable of directing lavage solution into the adapter (see fig 2 and supporting

text); and a valve device (74) configured in the adapter to substantially isolate the catheter from the manifold upon withdrawing the distal portion of the suction catheter into the adapter and applying suction through the catheter lumen (See fig 6 & supporting text) said valve device being opened by advancement of said suction catheter through said valve device (col. 4 lines 40-55) and a lavage port (40), but does not explicitly disclose the lavage port positioned to be in fluid communication with the annular space between the suction catheter and the adaptor when the suction catheter is present. However, Russo disclose such (See figs 5 & 6, lavage port 37/38). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Russo and used them with the device of Niermann. The suggestion/motivation for doing so would have been to permit suction catheter & adapter cleaning and sanitization while the device is in use. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 2, Niermann discloses the valve device as comprising a flap valve (note the flaps of element 74) disposed distal to a distal end of the collar.

In regards to claim 3, the flaps of Niermann are seated against the collar by dint of being attached to element 62, which is seated against the collar (32) throughout the operation, thus to include when the negative pressure is applied.

In regards to claim 4, the flaps of Niermann are fully capable of seating against the distal end of the suction catheter upon application of suction through the catheter lumen.

In regards to claim 5, Niermann substantially discloses the instant application's claimed invention to include a cleaning enclosure defined within the adapter (interior as defined by 62) wherein the distal end of the catheter is exposed to cleaning liquids, but does not explicitly disclose exposure to turbulent air flow during the cleaning procedure. However by use of suction and dint of the presence of gas in the cleaning enclosure, and the multiple openings present in the distal end of the catheter one of ordinary skill in the art would appreciate that the device of Niermann generates a turbulent airflow at the distal end when suction is applied.

In regards to claim 6, Niermann substantially disclose the claimed invention to include being capable of permitting turbulent air flow to originate from the slit/aperture of the valve. (When 32 is set in a position that would permit simultaneous fluid communication with both the valve and line 44 via alignment with 36)

In regards to claim 7, Niermann discloses the valve device (74) seated against the distal end of the collar. (See the interface between 74 & 32 by dint of element 62).

In regards to claim 10, the device of Niermann substantially discloses the instantly claimed invention as noted above in regards to the rejections to claims 1 & 5, and furthermore, discloses a

means that is fully capable of producing a predetermined rate of airflow to the enclosure responsive to negative pressure in the catheter (flow generator attachable to 24 that generates flow 25), the catheter being protected by the sleeve, adapter and enclosure from environmental contamination, the valve including a flap and a hinge (point of direct interface of either flap with the adapter) and where the flap is fully capable of occluding the catheter responsive to a pressure differential between the flap and the enclosure.

In regards to claim 11, the device of Niermann is fully capable of and does disclose in light of the understanding of one or ordinary skill in the art that the air flow rate in the device is responsive to negative pressure, i.e. flow is known to follow negative sloped pressure gradients, the greater/steeper the gradient the greater the flow rate induced by the negative pressure introduced.

3. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann & Russo as applied to claim 6 above, and further in view of Reynolds (US 5370610).

The suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a filter to filter airflow provided to the cleaning enclosure. However, Reynolds disclose such (# 64). The references are analogous since they are from the same field of endeavor, the medical arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Reynolds and used them with the suggested device. The suggestion/motivation for doing so would have been to reduce the possibility of infecting the patient by filtering out bacteria (See

Reynolds col. 9 line 50). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann, Russo & Reynolds as applied to claim 8 above, and further in view of Loescher et al (US 5005568).

The suggested device substantially discloses the instant application's claimed invention, to include a valved opening (62 of Reynolds) but does not explicitly disclose the use of a valve in conjunction with the filter in the same opening. However, Loescher disclose such (See the filter/valve combination). The references are analogous since they are from the same field of endeavor, the medical/respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Loescher and used them with the suggested device. The suggestion/motivation for doing so would have been to have better control over the air being permitted to enter the medical device's interior. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather

that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niermann & Russo as applied to claim 11 above, and further in view of Reynolds.

The suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose a filtered opening to ambient in the body of the cleaning enclosure. However, Reynolds disclose such (See # 64). The references are analogous since they are from the same field of endeavor, the medical arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Reynolds and used them with the suggested device. The suggestion/motivation for doing so would have been to reduce possible bacterial contamination during use/operation. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

6. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Aaron Lewis, can be reached at telephone number (703) 308-0716. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Jfweiss

April 28, 2003

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SUPERVISORY PATENT EXAMINER
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